Date: December 19, 1996

DSL-BQA-96-058

To: Ambulatory Surgical Centers ASC - 09

From: Judy Fryback, Director
Bureau of Quality Assurance

Medicare Definition of an Ambulatory Surgical Center (ASC) and other information.

Attached is a copy of a memorandum dated November 8, 1996, that we received from the Health Care Financing Administration, Chicago Regional Office. Besides a definition of what is an Ambulatory Surgical Center, this memorandum contains information compiled in response to questions from different providers. Items that are discussed include record keeping, mixing functions, transfer of non-Medicare patients, overnight stays for non-Medicare patients, seven questions and answers, and concludes with a discussion on Life Safety Code (LSC) issues.

Please share this information with your staff. Any questions you may have should be directed to Stephen D. Schlough, P.E., Chief, Health Services Section at (608) 266-3878.

JF/SDS/jjf

Attachments

Department of Health and Family Services
Region V
Health Care Financing Administration

MEMORANDUM

Date: November 8, 1996

From: Mark Dykstra, Program Representative

Subject: Medicare Definition of Ambulatory Surgical Center (ASC)

To: Stephen D. Schlough, Hospital & Health Services Section
Bureau of Quality Assurance
Wisconsin Department of Health and Family Services

Refer to: CO7

This is in response to your memo to Douglas Wolfe of August 29, 1995. We queried our Central Office (CO) regarding the issues you raised, and have received a response. This reply to you contains our best current understanding of these complex issues and you may proceed based upon it.

These issues were raised by Wausau Surgery Center (WSC), Wausau, Wisconsin, in consultation with the counsel for the Wisconsin Surgery Center Association, Sheila Reynolds. I am sending a copy of this memo to Ms. Reynolds.

First, your memo said WSC is routinely admitting non-Medicare patients for 23 hour stays in the ASC. This is not permitted in a certified ASC, as I will discuss below. However, the manner in which this was cited to the facility, via Medicare coverage regulations, was not correct.

The Medicare ASC coverage rules say ASC procedures generally require no more than four hours recovery time. Your surveyors referred to these rules in their August 18, 1995 Medicare survey of WSC. They cited the facility as not meeting the Medicare definition of an ASC based upon this coverage regulation at 42 CFR 416.65(b). However, these regulations do no define an ASC. They refer to the types of surgical procedures that the Medicare program will cover (pay for) if they are provided to a Medicare beneficiary in a certified ASC. Consequently, while these coverage rules are in harmony with the regulations containing the definition of an ASC, and shed worthwhile light on the definition, they are not themselves part of the definition.

A second item in your memo also has to do with the definition of an ASC. You quoted the Regional Office (RO) as saying that an "ASC is used exclusively for ASC services." We in the RO have used these, or very similar, words as a shorthand definition of an ASC. In doing so, we were paraphrasing the primary portion of the definition of an ASC found at 42 CFR 405.416.2, which reads:

> *Ambulatory surgical center* or *ASC* means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, has an agreement with HCFA to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.

(The regulation regarding recovery time that the surveyors cited, 42 CFR 416.65(b), is contained in Subpart D—Scope of Benefits.)

As you can see, the regulatory definition doesn't simply tie the meaning of "ASC" to the provision of ASC services, as the old RO shorthand suggests. Rather, the regulatory definition is more complex and has four key components:

1) An ASC is a "distinct entity." This means it cannot also be something else, such as a skilled nursing facility, a hospital, or, to use a category of entity referred to by the HCFA CO, it cannot also be a non-hospital post operative care facility or recovery center.

2) It "provid[es] surgical services." The definition doesn't at this point limit the types of surgical services provided.

3) It "operates exclusively for [one] purpose." The purpose for which it operates exclusively is the fourth key item.

4) It exists for the exclusive purpose of providing surgical services "to patients not requiring hospitalization." Page 2-61 of the SOM defines "hospitalization" in this context as "an inpatient stay in a hospital." The definition rules out planned transfers to a hospital for <u>any</u> patient (except in an emergency).

Because of the richness of meaning within the regulatory definition, it would be wise not to use the shorthand version of the definition that you quoted.

Third, you refer to two documents written by the HCFA CO that were attached to the facility's response to the deficiency cited in regard to four-hour recovery times. Both letters, one written in 1992 and the other in 1995, say that there is a way for a Medicare ASC to keep its patients overnight within the ASC. However, the HCFA CO has now seen that this view is not compatible with the ASC regulations, and is no longer taking that position. To clarify this policy transition, I will discuss the two letters, the SOM guidelines that were issues in 1993 and CO's recent answer to my query, which was occasioned by your memo.

The first of these is a letter from Robert Wren, Director, Office of Coverage and Eligibility Policy, Bureau of Policy Development, HCFA, to Dianne Millman of the Washington office of McDermott, Will & Emery, dated February 21, 1992. It says:

> We don't believe that current policy precludes a Medicare-certified ASC from operating an overnight unit (within the facility itself) and routinely referring non-Medicare [patients] for overnight stays, so long as the overnight unit is used exclusively for non-Medicare patients. In other words, a facility could "transfer" a non-Medicare patient for overnight care within the facility itself, without jeopardizing its certification. …
>
> We have been in touch with appropriate staff in that Bureau [of Health Standards and Quality] to assure that the revised [ASC} guidelines make clear that a "transfer" does not preclude a non-Medicare patient being moved to an overnight stay within the facility itself. These guidelines will be forthcoming in the near future.

Revised guidelines for ASCs came out in December, 1993 in State Operations Manual (SOM) Transmittal 262. However, rather than describing "transfers" taking place within an ASC, the guidelines upheld the regulatory concepts of distinctness and exclusivity. Just below is the entire December, 1993 guideline section for the definition of an ASC from page L-2 of the SOM:

> The ASC must used its space for ambulatory surgery exclusively.
>
> Record keeping must be exclusive to the ASC, and the staff must be responsible to the ASC. For example, a nurse could not provide coverage in the ASC and in an adjacent clinic (or hospital) at the same time. The ASC is not required to be in a building separate from other health care activities (e.g., hospital, clinic, physician's office). It must be separated physically by at least semi-permanent walls and doors.
>
> The regulatory definition of an ASC does not allow the ASC an another entity to mix functions and operations in a common space during concurrent or overlapping hours of operation. Another entity may share <u>common space</u> only if the space is never used during the scheduled hours of ASC operation. However, the operating and recovery rooms must be used exclusively for surgical procedures.
>
> The ASC may not perform a surgical procedure on a Medicare patient when, before surgery, an overnight hospital stay is anticipated. There may, however, arise unanticipated medical circumstances that warrant a Medicare patient's hospitalization after an ASC surgical procedure. The ASC must have procedures for the immediate transfer of these patients to a hospital (42 CFR 416.41). Such situations should be infrequent.
>
> ASC covered procedures (see 42 CFR 416.65) are those that generally do not exceed 90 minutes in length and do

not require more than four hours recovery or convalescent time. Thus, ASC patients generally do not require extended care as a result of ASC procedures. An unanticipated medical circumstance may arise that would require an ASC patient to stay in an overnight healthcare settings. Such situations should be infrequent. When extended care in a non-hospital healthcare setting is anticipated as a result of a particular procedure, that procedure would not be a covered ASC procedure for Medicare beneficiaries.

This 1993 SOM revision did not pick up the "transfer within the facility" concept from Mr. Wren's February 21, 1992 letter. Nevertheless, the concept reappeared in the June 26, 1995 letter that was the second document attached to WSC's plan of correction. This letter was from Vivian Braxton, Director, Division of Outpatient Surgery and Services, Office of Physician and Ambulatory Care Policy, Bureau of Policy Development, HCFA, to Sheila Reynolds. It says:

> …ASCs may transfer non-Medicare patients to overnight recovery care facilities, other than a hospital, without jeopardizing Medicare certification. Moreover, such a transfer for overnight care may be to a distinct part entity located within the ASC itself. We do not require a fire wall to separate space used for overnight care of non-Medicare patients from the rest of the ASC facility.

The most recent policy statement regarding this issue, however, reverses the above statement and now parallels the SOM guidelines. In a May 30, 1996 memo to this office, Terri Harris of HCFA's Division of Outpatient Surgery and Services, Office of Physician and Ambulatory Care Policy, Bureau of Policy Development, says the following:

> There is no category of distinct part entity for an ASC. The ASC is a distinct entity physically and financially identifiable from another entity. Two different entities can own the ASC and occupy the same space. However, these entities cannot mix functions during the ASC's hours of operation. The ASC can become another entity (i.e., overnight recovery center) after the [Medicare] ASC is closed. …
>
> As stated in the previous answer, there is no category for a distinct part entity. The parent corporation can own two other corporations, however, the ASC is a distinct entity by itself. The ASC cannot be an overnight recovery center or any other entity during [its] hours of operation. If the ASC is used as another entity during their hours of operation, they would be out of compliance with the definition of an ASC.

This guidance indicates that a Medicare ASC cannot keep any patients overnight, as was the Wisconsin facility about which you wrote. If that ASC, or any other, is keeping patients overnight, it is out of compliance with the ASC definition regulation.

The question now becomes, exactly what can a Medicare ASC do, and what is it prohibited from doing, in regard to other entities, Medicare and non-Medicare patients and overnight stays? Before summarizing the answer to that question, I must discuss a related issue that your memo did not raise, but which is important.

The issue is that of a Medicare ASC sharing staff, space and other things with a non-Medicare ASC. An ASC will have fewer restrictions regarding its patients if it can deal with them outside of the Medicare regulatory context. Some ASCs, therefore, will function as a Medicare entity only during certain hours in a certain location. Another (related) entity, the non-Medicare ASC, will function in the same, or an overlapping, location during different hours.

We have received guidance from our CO on this issue. This guidance took the form of answers to questions that we posed in the case of a non-Medicare ASC that leased its premises to a Medicare ASC for one day per week. The seven numbered questions and answers from our CO's January 7, 1994 memo to us are shown below. First, however, I will show the wording from SOM 2210 that question number one refers to:

> Participation as an ASC is limited to any distinct entity that operates <u>exclusively</u> for the purpose of providing surgical services to patients not requiring hospitalization (i.e., an inpatient stay in a hospital). The ASC may share <u>common space</u> with another hospital function only if the space is never used by the other party during the scheduled hours of ASC operation. The operating room(s) and recovery room(s) are to be used only for patients having surgery.

1. Q. Does the prohibition against an ASC operating simultaneously in shared space with another entity, contained in State Operations Manual (SOM) section 2210, preclude both these entities from operating ini

the same space on the same day?

A. No. Both ASCs may operate in the same space on the same day; however, the entities are precluded from operating concurrently in the same space on the same day. (See SOM, Appendix L, section 416.2 Definitions [quoted in full in this memo, beginning on page 3]).

2. Q. If they can operate simultaneously, what instructions should be given to the carrier to prevent the facilities from double-billing for the same patients?

A. Answered by response to question 1.

3. Q. Must each entity have its own staff, equipment and medical records?

A. Yes. Staff, equipment and record keeping must be separate and exclusive to each entity during each entity's hours of operations. (See the SOM, Appendix L, section 416.2 Definition.)

4. Q. Can the one-day-a-week ASC share, lease, or employ the staff of the other ASC?

A. Yes.

5. Q. If the one-day-a-week ASC shares staff, equipment, or records with the other ASC, how does it meet the regulatory requirement that it be a "distinct entity", found in the definition of an ASC at 42 CFR 416.2?

A. The entities cannot concurrently share staff, equipment and record keeping. They must meet the definition by operating separately and independently and exclusive of each other during each ASC's hours of operation. Record keeping should not be shared under any circumstances.

6. Q. Can the one-day-a-week ASC's day of operation ever vary?

A. Yes, there are no requirements which prohibit the entities from varying their day of operation.

7. Q. Is there a limit to the number of days per week such a lease arrangement can be in effect, and if so, what is it?

A. There are no requirements which limit the number of days per week a lease arrangement can be in effect.

Finally, I must also address a relevant Life Safety Code (LSC) issue. 42 CFR 416.44(b) requires that an ASC meet the provisions of the 1985 edition of the LSC of the National Fire Protection Association that apply to ambulatory surgical centers. (An ASC that met the 1981 edition of the LSC on May 9, 1988 and continues to do so, is grandfathered.)

Two of the applicable portions of the 1985 LSC are Chapter 12, Section 12-6, New Ambulatory Health Care Centers and Chapter 13, section 13-6, Existing Ambulatory Health Care Centers. These portions of the LSC apply to the distinct entity that is the Medicare ASC, regardless of whether or not it shares space with another entity (which it can do only when the other entity is not in operation).

Both section 12-6.3.7.1 (applicable to newly constructed ASCs) and 13-6.3.7.1 (applicable to existing ASCs of the 1985 LSC say:

> Ambulatory health care occupancies shall be separated from other tenants and occupancies by walls having at least a 1-hour fire resistance rating.

(The same sections of the 1981 code are virtually identical.)

The Medicare ASC must be a separate and distinct entity, legally, operationally and physically. If other entities are also occupants of a building in which a Medicare ASC is located, the Medicare ASC must be separate from them. Based on the LSC requirement quoted above, the physical separation must be a wall with at least a 1-hour fire resistance rating.

For convenient future reference, I will itemize some of the conclusions from the above discussion:

A Medicare ASC cannot--

- preplan the transfer of any patient to a hospital for recovery;
- allow overnight stay by any patient within the Medicare ASC during its hours of operation;
- preplan overnight stay anywhere for Medicare patients;
- operate in the same space during the same time with any other entity;
- concurrently share staff, equipment or records with any other entity.
- allow its operating and recovery rooms to be used, at any time, by any entity, for anyone other than surgery patients.

A Medicare ASC can--

- preplan the transfer of a non-Medicare patient to a nursing facility or other non-hospital facility for overnight recovery.

A Medicare ASC must--

- maintain its own, exclusive medical records.
- be enclosed by walls having 1-hour fire resistance if it occupies only part of a building.

As always, if you have any questions regarding either this memo or a particular case, feel free to call me at (312) 886-5217.